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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/367,950 08/18/99 EKSTROM

T 06275/188001

EXAMINER

HM22/0521

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ART UNIT	PAPER NUMBER

1617  
DATE MAILED:

7  
05/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/367,950

Applicant(s)

EKSTROM, TOMMY

Examiner

Jennifer M Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

**DETAILED ACTION**

1. Applicant's arguments filed April 20, 2001 have been fully considered but they are not persuasive.

Applicants' arguments are:

- a. There is no recognition in the Carling reference that the budesonide/formoterol compositions described therein would be suitable for use on an "**as needed**" basis, much less that their use in this manner would be advantageous.
- b. The secondary references do not supply a teaching or suggestion of the use of budesonide/formoterol compositions on an "as needed" basis, instead, these references are cited to provide teachings that (R,R)-formoterol and the 22R epimer of budesonide.

However, as the Applicant admit that Carling stated that "the intended dose regimen is a **twice daily** administration". Applicant's claiming "as needed" administration of budesonide/formoterol compositions encompass "twice daily" administration, for example, for some patients twice a day administration of the composition can be their "as needed" daily dosage. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

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In view of the above Office Action of December 18, 2000 is deemed proper and asserted with full force and effect herein to obviate applicant's claims.

*Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 13-15, 17-18, and 20-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling et al. (WO 93/11773) of record.

3. Carling et al. at page 8-14, page 3, line 35 through page 4, line 10, lines 30-35, page 6, lines 5-30, and page 7, lines 1-5, teach a composition comprising Applicant's active agents use for treating respiratory disorder such as asthma set forth in claims 13-15, 17-18, 20-21, and 23.

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4. Carling et al. at page 4, lines 3-10, also teach that the combination of formoterol and budesonide has not only a greater efficiency and duration of bronchodilator action but a rapid onset of action.

5. The difference between Carling et al. and Applicant's invention is a specific carrier set forth in claim 24, the molar ratio of active agents set forth in claim 14, the particle size set forth in claim 22, the ratio, and the amounts of active agents set forth in claims 25-29, instructing the patient to schedule to use with other agents, or with other asthma triggering events set forth in claims 30-34.

However, the molar ratio and the amounts of active agents to be used, the selection of carrier, and the particle size of active agents, providing instruction to the patient to schedule to use with other agents, and instruction for prior use to prevent from other asthma triggering events are all deemed obvious since they are all within the knowledge of the skilled pharmacologist.

Claims 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling et al. (WO 93/11773) of record in view of Hett et al. (Org. Process Res. Dev., 1998) and Ryrefeldt et al. (Biochem. Pharmacol., 1989).

See paragraph 3, above, for teachings of Carling et al.

Hett et al. teach at the abstract that (R,R)-Formoterol is a long-acting, very potent  $\beta$ -agonist, which is used as a bronchodilator in the therapy of **asthma**.

Ryrfeldt et al. teach at the abstract that **22R epimer of budesonide** is more potent in the treatment of bronchial **asthma** than 22S epimer.

The claims differ from the cited references in claiming a combination of (R,R)-Formoterol, and **budesonide**, (claim 16) and a combination of Formoterol and **22R epimer of budesonide** (claim 19) to treat asthma. To employ combinations of (R,R)-Formoterol, and **budesonide**, (claim 16) and a combination of Formoterol and **22R epimer of budesonide** (claim 19) to treat asthma would have been obvious because both components are well known, and potent active agents individually for treating asthma. It would be expected that the combination of components would treat asthma.

The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069 (CCPPA 1980)).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as

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represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

The data has been reviewed but is not deemed persuasive as there is lack of synergistic action or surprising and unexpected result.

None of the claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

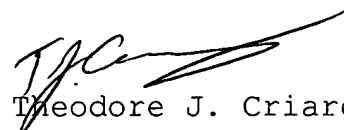
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is (703) 308-2232. The examiner can normally be reached on Monday through Friday from 9 AM. to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Theodore J. Criares  
Primary Examiner  
Art Unit 1617

jmk  
May 4, 2001